



6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

**[FRL-9808-6; Docket ID No. EPA-HQ-ORD-2009-0398]**

### **Toxicological Review of Methanol (Non-Cancer):**

### **In Support of Summary Information on the Integrated Risk Information System (IRIS)**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of a public comment period and peer review on the draft non-cancer toxicological review of methanol.

**SUMMARY:** EPA is announcing a 45-day public comment period and peer review on the draft toxicological review titled “Toxicological Review of Methanol (Non-Cancer): In Support of Summary Information on the Integrated Risk Information System (IRIS)” (EPA/635/R-11/001Ba). The public comment period begins on or about May 3, 2013, and ends June 17, 2013. EPA will announce the date, time, and procedures for public participation in the peer review in a separate Federal Register Notice, or in an announcement on the IRIS website. EPA is releasing this draft assessment for the purpose of public comment and peer review. This draft assessment is not final, as described in EPA’s information quality guidelines, and it does not represent and should not be construed to represent Agency policy or views.

**DATES:** The public comment period on the draft Toxicological Review of Methanol (Non-Cancer) begins on or about May 3, 2013, and ends June 17, 2013. The draft review is posted to the IRIS website at <http://www.epa.gov/IRIS>. Comments should be in writing and received by EPA by June 17, 2013. Comments received by June 17, 2013, will be provided to the peer reviewers for their consideration.

**ADDRESSES:** The draft toxicological review titled “Toxicological Review of Methanol (Non-Cancer): In Support of Summary Information on the Integrated Risk Information System (IRIS)” is available primarily via the Internet on the IRIS website at <http://www.epa.gov/IRIS>. A limited number of paper copies are available from the Information Management Team (Address: Information Management Team, National Center for Environmental Assessment [Mail Code: 8601P], U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone: 703-347-8561; facsimile: 703-347-8691). If you request a paper copy, please provide your name, mailing address, and the draft assessment title. Comments may be submitted electronically via <http://www.regulations.gov>, by e-mail, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions provided in the SUPPLEMENTARY INFORMATION section of this notice.

**ADDITIONAL INFORMATION:**

For information on the draft assessment, please contact Jeffrey Gift, Ph.D, U.S. Environmental Protection Agency, National Center for Environmental Assessment, Mail Code B243-01, 109 T.W. Alexander Drive, Durham, NC 27711; telephone: 919-541-4828; facsimile: 919-541-0245; or e-mail: [gift.jeff@epa.gov](mailto:gift.jeff@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Background:**

The draft toxicological review was prepared by the National Center for Environmental Assessment (NCEA) within the EPA Office of Research and Development (ORD). The public has been provided an opportunity to comment on previous external review drafts of the IRIS toxicological review of methanol. In January 12, 2010, EPA released an external review draft (EPA/635/R-09/013), containing both cancer and non-cancer analyses, for public comment. EPA later placed this external review on hold pending resolution of issues concerning a specific set of data used in the cancer analysis. On April 18, 2011, EPA released for public comment another external review draft (EPA/635/R-11/001) which contained only a non-cancer analysis. The data and studies used in the non-cancer analysis are unrelated to the issues concerning the cancer analysis. On June 22, 2011, EPA released an addendum to the April 18, 2011, non-cancer external review draft to provide the public an opportunity to comment on the incorporation of several new studies into the analysis. On July 22, 2011, Eastern Research Group (ERG), an EPA contractor for external scientific peer review, convened an independent panel of experts to conduct a public peer review meeting on the non-cancer external review draft of the toxicological review of methanol released on April 18, 2011, (EPA/635/R-11/001) and the addendum released on June 22, 2011.

The current draft toxicological review titled “Toxicological Review of Methanol (Non-Cancer): In Support of Summary Information on the Integrated Risk Information System (IRIS)” (EPA/635/R-11/001Ba), which will be posted on NCEA’s website, has been revised in response to the peer review and public comments received on the external review draft released

on April 18, 2011, and the June 22, 2011, addendum. This notice announces a new public comment period on the current revised draft toxicological review in advance of an upcoming peer review and in accordance with applicable information quality guidelines. The external peer review comments and EPA responses on the previous draft assessment are summarized in Appendix A of the draft. EPA is releasing this draft assessment for the purpose of public comment and peer review. This draft assessment is not final, as described in EPA's information quality guidelines, and it does not represent and should not be construed to represent Agency policy or views.

In addition to a second opportunity for public comment announced in this notice, EPA will also schedule a follow-up external letter peer review of the draft toxicological review of methanol and will announce the details of the peer review in an additional federal register notice or on the IRIS website. To the extent possible, the Agency intends the follow-up peer review to be conducted by the same experts that served on the July 22, 2011, peer review panel. The public comments received during the comment period announced in this notice will be provided to the experts that will conduct the follow-up letter peer review. The peer reviewers will be asked whether EPA adequately responded to the comments from the July 22, 2011, peer review panel. The letter peer review will include a public teleconference with a limited opportunity for the public to address the peer reviewers. EPA will announce the date, time and procedures for public participation in the teleconference in a separate Federal Register Notice or in an announcement on the IRIS website.

## II. Information about IRIS

EPA's IRIS is a human health assessment program that evaluates quantitative and

qualitative risk information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic noncancer health effects and cancer assessments. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances and thereby support risk management decisions designed to protect public health.

### III. How to Submit Comments to the Docket at <http://www.regulations.gov>

Submit your comments, identified by Docket ID No. EPA-HQ-ORD-2009-0398, by one of the following methods:

- <http://www.regulations.gov>: Follow the on-line instructions for submitting comments
- E-mail: [ORD.Docket@epa.gov](mailto:ORD.Docket@epa.gov)
- Facsimile: 202-566-9744
- Mail: Office of Environmental Information (OEI) Docket (Mail Code: 28221T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460. The telephone number is 202-566-1752. If you provide comments by mail, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an

index, number pages consecutively with the comments, and submit an unbound original and three copies.

- Hand Delivery: The OEI Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202-566-1744. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by hand delivery, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

*Instructions:* Direct your comments to Docket ID No. EPA-HQ-ORD-2009-0398.

Please ensure that your comments are submitted within the specified comment period.

Comments received after the closing date will be marked "late," and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at <http://www.regulations.gov>, including any personal information provided, unless comments include information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through <http://www.regulations.gov> or e-mail. The <http://www.regulations.gov> website is an "anonymous access" system, which means that EPA will not know your identity or contact

information unless you provide it in the body of your comments. If you send e-mail comments directly to EPA without going through <http://www.regulations.gov>, your e-mail address will be automatically captured and included as part of the comments that are placed in the public docket and made available on the Internet. If you submit electronic comments, EPA recommends that you include your name and other contact information in the body of your comments and with any disk or CD-ROM you submit. If EPA cannot read your comments due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comments. Electronic files should avoid the use of special characters and any form of encryption and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

*Docket:* All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically at <http://www.regulations.gov> or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Dated: April 26, 2013.

Cheryl G. Itkin,  
Acting Director, National Center for  
Environmental Assessment.

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